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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/502,511

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Hirosige Nakatsuka

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EXAMINER

THEXTON, MATTHEW

ART UNIT

PAPER NUMBER

1714

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/502,511

Applicant(s)

NAKATSUKA ET AL.

Examiner

Matthew A. Thexton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 13-26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date one sheet.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2006 June 29 has been entered.

Information Disclosure Statement

The IDS submitted 2006 June 29 has(have) been considered. Duplicate citation(s) has(have) been lined through, retaining the earlier(earliest) filed citation(s).

The foreign language documents submitted with English language abstracts have only been considered to the extent they are understood from said abstracts.

The document DE 4344141C1 was submitted without an English abstract and the citation to it has therefore been lined through. An English language abstract to WO 95/17157A2 was considered and is thought to correspond to this document.

Priority Date Established

Applicant's submission of certification of a true and complete translation of the priority document, which statement was submitted with the English language

specification, is noted. Applicant is entitled to the filing date of the priority document, 2002 January 23.

Text of Title 35 USC not Cited

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The specification has trademarks too numerous to catalog. Applicant's assistance is required to insure that corrections are made. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. They should be CAPITALIZED wherever they appear and be accompanied by the generic terminology.

Applicant should note however, that the Examiner will allow amendment of the specification only when accompanied by a proper showing that the amended subject matter is what the trademarks represent, e.g., data sheets from manufacturer, with publication date prior to the earliest filing date.

Appropriate correction is required.

Claim(s) Version

The listing of claims submitted in the paper filed 2006 June 29 has been examined.

Claim(s) Analysis

Claims 1-12 have been canceled.

Independent claim 13 is directed to methods of blocking or reducing adverse effects of x-rays, gamma rays or electron beams to a subject comprising:

“determining” a subject will be exposed to 10 kGy or more of said x-rays, gamma rays and/or electron beams; and

“protecting” the subject with material comprising at least one member from the group consisting of collagens, keratins, silk fibroins and their derivatives.

Dependent claims 14-19 further require:

(14/13) that the member “is administered to, mixed with, coated on or immobilized on the subject”;

(15/13) that “a subject” is protected by “a radioprotective plastic product, radioprotective film, radioprotective sheet, radioprotective coating agent, radioprotective cosmetic product, or radioprotective fiber comprising at least one member selected from the group...is used to protect the subject”;

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(16/15) that "a product" comprising the member "is place over, applied to or administered to the subject";

(17/13) that the member "is present inside the subject or inside the surface layer of a subject in a total amount of 0.05 wt.% to 40 wt%";

(18/13) that "the subject" is selected from the group consisting of "agricultural products, marine products, foods, domestic animals, pets, electronic precision instruments, textiles, medical and experimental materials";

(19/13) "wherein the subject is a human."

Independent claim 20 parallels claim 13 but is directed only to electron beams and the degree of exposure limitation is not stated.

Dependent claims 21-26 parallel claims 14-19.

The limitation of "10 kGy" without specifying the amount of the body exposed and the time of exposure is inchoate (Salvato, Joseph A. "Environmental Engineering and Sanitation," p. 858-9). 10 kGy is 10 kJ/kg, but the amount of subject exposed (kg) and the length of time of exposure is not specified. As set forth, the exposure could be for a microsecond and to a microgram of the subject; for which it is clear that no protection is measurably needed or afforded.

Claim Rejections - 35 USC § 112

Claims 13-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not indicated where in the specification there is support for, nor has such been located, the step of “determining that a subject will be exposed to 10 kGy or more of said x-rays, gamma rays and/or electron beams.” As noted elsewhere, the specifying of “10 kGy” without specifying the amount of the body exposed and the time of the exposure renders this limitation inchoate. Although, Applicant asserts (response of 2006 June 29, page 4, last full paragraph) that the original specification describes that “miners, flight crews, astronauts, military personnel, radiological technologists and radiation facility workers” in such environments as “radiation facilities...mines” may be exposed to radiation, this is not the same as a written description of the noted limitation of the claims. There is no evidence of record that such persons in such activities would be exposed to 10 kGy of the noted sources. There is no description of how to ‘determine.’ Lastly, there is no support for “or more.” The original specification employs “10 kGy,” but such does not afford any conclusion as to more or less than this.

Claims 13-26 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The means of “determining” and the meaning of “10

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kGy" are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The requirement of "determining" is made without any enabling guidance. In addition, the meaning of "10 kGy" without specifying the amount of the subject and the length of time is inchoate since a dose is the critical aspect of exposure and thus this recitation fails to enable one to practice the claimed invention (Salvato, Joseph A. "Environmental Engineering and Sanitation," p. 858-9).

Claims 13-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The experiments set forth in the disclosure comprise exposing highly dilute aqueous solutions of test material mixed with a-amylase to x-ray, gamma ray, or electron beams for undefined lengths of time. The a-amylase is then evaluated in a potato starch solution for the length of time it takes to go to complete reaction, and this compared to time for an unexposed standard. There is no disclosure or evidence of record that the reduction of a-amylase activity correlates or corresponds to evidence that humans or inanimate objects can be protected from similar exposures. Providing a nexus between the tests performed and Applicant's assertion or conclusion that the test materials are evidencing radiation shielding is required; particularly since acute whole-body exposure to 10 kGy (1,000,000 rad) would

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most likely be fatal (Salvato, *ibid*) (Pfafflin et al., "Encyclopedia of Environmental Science and Engineering," p. 1109). The fact that α -amylase activity is affected differently when in aqueous solutions with various test materials after exposure to radiation does not demonstrate or imply that completely different, non-aqueous mixtures of the test materials mixed with the various carriers described (and encompassed by claim 15), would attenuate rays which are well known to pass through objects (Salvato, *ibid*, p. 851, "x rays and gamma rays"). Applicant asserts (response of 2006 June 29, page 4, last full paragraph) that the original specification describes that "miners, flight crews, astronauts, military personnel, radiological technologists and radiation facility workers" in such environments as "radiation facilities...mines" may be exposed to radiation. These involve whole body exposures for several hours, under which conditions Applicant provides no evidence that the claims' limitation of "protecting" the subject with "collagens, keratins, silk fibroins and their derivatives" is accomplished. If 600 rad (0.006 kGy) exposure in one day would be fatal (Salvato, p. 858-9), then common sense and the public interest dictates that potential exposure to 10 kGy (1,000,000 rad) over several hours would require proof of efficacy.

Claims 13-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation of "10 kGy" without specifying the amount of the body exposed and the time of exposure is inchoate (Salvato, Joseph A.

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"Environmental Engineering and Sanitation," p. 858-9); implying a limitation without actually being one.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim refers to "a subject" (second occurrence of subject) while the claim from which it depends already recites "a subject." It is unclear if Applicant intends to introduce a new subject or intends to rely upon the antecedence of 'the' subject of claim 13.

Claims 17 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite an amount of "0.05 wt% to 40 wt%" but it is unclear to what this refers, the member the surface layer, or the subject.

Claim(s) Rejection(s) - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16, 17, 23 and 24 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. It flies in the face of reason that "the subject" can be protected by using the alleged shield from the "inside" of the

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subject. To the extent that “administered to” is meant to mean placing inside such as by swallowing, then “the subject” is not protected and the claims are inoperative. To the extent that “the subject” may be comprised of parts having multiple layers and the shield may be “inside a [or the] surface layer of a (sic) [or the] subject” while not inside other parts, then “the subject” is not protected and the claims are inoperative.

Claim(s) Rejection(s)

Claims 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talty, J. T., (“Industrial Hygiene Engineering – Recognition, Measurement, Evaluation and Control (2nd Edition)”).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

The reference (p. 665, Table, and p. 694, first paragraph) discloses leather is effective shielding against beta radiation. Further, it is well known that beta radiation is variable, but relatively easily shielded against with low atomic weight materials (p. 679-680) which suggest carbon, hydrogen, nitrogen, and oxygen, all presents in collagens, keratins, silk fibroins.

Response to Arguments

Applicant's arguments filed 2006 June 29 have been fully considered but they are not fully persuasive.

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Applicant's arguments with respect to the rejection under 35 USC 112, first paragraph, new matter (page 4 of response), have been fully considered but they are not persuasive. It is thought that Applicant's arguments have been addressed in the statement of rejection hereinabove.

Applicant's arguments with respect to the rejections based on the premise that the claims encompass exposure to Earth level background radiation have been fully considered and are persuasive to the extent that no place experiences 10 kGy. These rejections have been withdrawn.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew A. Thexton whose telephone number is 571-272-1125. The examiner can normally be reached on Tuesday-Friday, 10:00 to 7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasudevan S. Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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